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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/148,234	09/04/1998	IOANNIS MOUTSATSOS	GI5298A	3002

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/148,234	Applicant(s) MOUTSATSOS ET AL.	
	Examiner Gerald G Leffers Jr., PhD	Art Unit 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 24 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 24-28.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Gerald G Leffers Jr., PhD
Primary Examiner
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Advisory Action Attachment

Receipt is acknowledged of a supplemental After-Final Amendment, filed 11/24/2004, in which it was proposed that claims 24-27 be amended. Claims 24-28 are pending and under consideration in the instant application.

Continuation of 2. NOTE: The proposed addition of the term "organized" to claim 24 raises new issues with regard to the metes and bounds of the term and also requires a new search. In their response to the Advisory Action mailed on 10/12/2004, applicants argue that the term is supported and defined in the instant specification and that it does not broaden the scope of the claimed invention. Consequently, it is argued, the proposed amendment should be entered and applicants' arguments directed to the amended claims considered.

The response is correct in noting that the proposed addition of the term "organized" to the claim does not broaden the scope of the claimed invention. Addition of the term does raise new issues for consideration, however, and still requires a new search of the prior art because the term and concept of "organized" functional bone formation was not specifically claimed in the prior set of claims. Addition of this new concept requires reconsideration of the prior art of record. It necessitates a new search of the prior art to determine whether any other prior art might read on the newly claimed subject matter and to determine if there is an art accepted definition of what is encompassed by the term.

While the passages cited in applicants' response (e.g. page 25, lines 12-21; page 26, lines 12-14) do in fact provide 35 USC 112 1st paragraph support for the concept of "organized" bone formation at a site of bone infirmity, they do not provide an explicit and limiting definition such

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that one of skill in the art necessarily knows the metes and bounds of the new term. For example, the first passage cited by applicants' response says that the observed bone formation is "well organized" and is characterized by growth of bone and cartilage within the boundaries of the fracture edges. In addition, the "well organized growth" is characterized by a collar of differentiating and calcifying chondrocytes formed around the original edge of the bone defect. The second passage cited in the response teaches that after transplantation of cells according to the claimed method, bone and cartilage formed around the fracture edge that appeared organized and oriented according to the original pattern of radial bone, thus better reconstructing the original structure. Finally, the response cited the Merriam-Webster dictionary as teaching one meaning of the term "organize" is to cause something to develop an organic structure, or to form into a coherent unity and functioning whole. The response argues that applicants have clearly demonstrated the formation of bone tissue in their working examples that is part of a coherent unity and functioning whole.

As indicated above, these definitions are not limiting. For example, to what extent does the tissue have to be "organized" in both qualitative and quantitative terms? What is the difference between the term "well organized" and "organized" as presented by the specification? Would the presence of some growth of bone or cartilage within the boundaries of the fracture edges satisfy the term limitation of being "organized"? Must the observed growth form a "collar" of differentiating and calcifying chondrocytes around the edge of the original defect? Or must the new bone and cartilage growth be oriented according to the original pattern of radial bone? Finally, if one considers the dictionary definition to mean that the new bone or cartilage tissue must form into a coherent unity and be part of a functional whole, it is difficult to see how

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the term modifies the concept of “functional” bone formation. This is an important issue as applicants are attempting to distinguish their invention from the prior art at least in part by arguing that there would have been no expectation of success in using the teachings of the prior art to obtain the type of “organized, functional bone formation” observed in their experiments.

Continuation of 5. does NOT place the application in condition for allowance because:

Arguments directed to the amended claims are moot since the proposed amendment has not been entered into the application. Each of the arguments directed against rejection of the pending claims over the prior art are directed to the amended claims (e.g. as summarized on page 8, last paragraph) and have not been further considered.

With regard to arguments directed to the New Matter rejection of claims 24-28 for comprising the term “mesenchymal stem cell”, it is argued that the use of the cell line C3H10T1/2 in the working examples of the instant application provides support for this term in the claimed methods. This is not accurate. The examiner concedes that it is likely true that the skilled artisan would recognize that the C3H10T1/2 cell line is an example of a murine mesenchymal progenitor cell line. The examiner does not concede, however, that recognition of the pluripotent character of the C3H10T1/2 cell line provides literal or inherent descriptive support for claiming the entire genus of cells that are encompassed by the term “mesenchymal stem cell”. Such cells can be obtained in a myriad of different ways from different sources and have a number of structural/functional characteristics (e.g. ability to respond to different factors to differentiate along different functional pathways). Therefore, the claims do comprise impermissible new matter and remain rejected for reasons of record.

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Conclusion

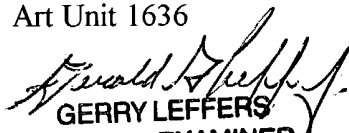
The proposed amendment of the claims has not been entered. Claims 24-28 remain rejected for reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636


GERRY LEFFERS
PRIMARY EXAMINER

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